

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2674. Adulteration of isotonic solution of sodium chloride and distilled water.
U. S. v. 228 Bottles, etc. (F. D. C. No. 26254. Sample Nos. 46890-K, 46891-K.)

LIBEL FILED: January 3, 1949, Western District of New York.

ALLEGED SHIPMENT: On or about November 16, 1948, by Readyflask, Inc., from Lakewood, Ohio.

PRODUCT: 228 bottles of *isotonic solution of sodium chloride* and 356 bottles of *distilled water* at Buffalo, N. Y. Each bottle contained 50 cc. The products were packaged in flasks of a type intended for the administration of injections.

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be "Sterile Isotonic Sodium Chloride Solution for Parenteral Use" and "Water for Injection," respectively, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, and their quality and purity fell below the official standards since they were contaminated with undissolved material.

DISPOSITION: February 1, 1949. Default decree of condemnation and destruction.

2675. Adulteration of water for injection. U. S. v. 988 Vials * * *. (F. D. C. No. 26280. Sample No. 7856-K.)

LIBEL FILED: January 17, 1949, Western District of New York.

ALLEGED SHIPMENT: On or about October 23, 1948, from Decatur, Ill.

PRODUCT: 988 100-cc. vials of *water for injection* at Buffalo, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the product purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The product was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: February 16, 1949. Default decree of condemnation and destruction.

2676. Adulteration of Hepafer Vitamin B₁. U. S. v. 1 Box * * *. (F. D. C. No. 26388. Sample No. 4849-K.)

LIBEL FILED: January 6, 1949, District of Massachusetts.

ALLEGED SHIPMENT: On or about December 11, 1948, by Carlo Erba New York, Inc., from New York, N. Y.

PRODUCT: 1 box containing 72 ampuls of *Hepafer Vitamin B₁* at Springfield, Mass.

LABEL, IN PART: (Box) "Hepafer-Vitamin B₁ #2 * * * a sterile aqueous solution * * * Dosage and Administration: Intramuscularly"; (ampul) "Hepafer With Vitamin B₁ #2 * * * Intramuscular."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, since the article purported to be and was represented as an aqueous solution intended for injection intramuscularly and was not suitable for such use. The